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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,237	10/19/2000	David S. Wells	085747/0170	5026

7590 11/20/2001

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 11/20/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/691,237

Applicant(s)

WELLS ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,7</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Receipt of the following is acknowledged:

1. Declaration and fee, dated 1-3-01
2. Specification dated 1-3-01
3. IDS dated 2-8-01
4. Preliminary amendment A, dated 9-28-01, and
5. IDS dated 9-28-01

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 14-20, 22-27 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al (5,582,838) OR Rork in view of Balandrin et al (5,506,268) OR Balandrin in view of Rork et al.

Rork teaches sustained release formulations, such as tablets, comprising a compressed core and a coating around the core. The core comprises a mixture of physiologically active agent and a polymer such as sodium acrylate polymers or carboxymethylenes prepared from acrylic acid cross-linked with allylic ethers, that on hydration forms polymer gel beads (claims and col. 4, lines 53-68). The formulations delivers drug at a constant rate over four to twenty-four hour period (see figures). Rork suggests a number of physiologically active substances in their

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formulation, which include hypnotics and sedatives such as diethylisovaleramide or bromoisovaleryl-urea. The admixture of drug and polymer reads on the matrix of the instant claims. Rork also teaches that the coating around the core is impermeable and insoluble and forms films (col. 11) and the coating includes plasticizers (claims). Further, Rork teaches polymer coating be made of polymers such as ethyl cellulose, cellulose acetate etc (claim 11). Rork does not explicitly teach that the matrix dissolves slowly or resists hydration. However, absent evidence on contrary, the polymer of Rork also dissolves slowly because the polymer of Rork also forms a gel as in the instant claims. Rork teaches that any pharmaceutically active agent can be used in their sustained formulation and in particular mentions sedatives and hypnotics such as diethylisovaleramide. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to prepare sustained release formulations of diethylisovaleramide, by preparing a core comprising diethylisovaleramide and a gelling polymer, surrounded by a film coating, with an expectation to provide a constant and sustained release of diethylisovaleramide, such that the sedation or hypnotic effect of diethylisovaleramide is achieved for a long period of time. Rork teaches diethylisovaleramide and not isovaleramide. However, instant claim 1 recites a pharmaceutically acceptable amide of isovaleric acid, which includes the diethylisovaleramide of Rork.

Balandrin teaches isovaleramide as an anxiolytic agent and a sedative and suggests using it for the treatment of central nervous disorders such as tension, restlessness, inability to concentrate, over-aggressiveness etc (col. 6). Balandrin teaches oral administration of isovaleramide in the form of tablets, capsules or drops etc (col. 7). Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use isovaleramide of Balandrin

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or diethylisovaleramide of Rork in the sustained release composition of Rork with an expectation to provide a prolonged therapeutic effect for the treatment of CNS disorders taught by Balandrin.

Alternatively, Balandrin teaches isovaleramide for a number of other CNS disorders, but does not teach sustained release compositions. However, it would have been obvious for a skilled artisan at the time of the instant invention to use the sustained release polymer and film coating s of Rork in preparing a formulation of isovaleramide of Balandrin, with an expectation to provide a sustained release of isovaleramide for a prolonged treatment of CNS disorders such as anxiety, restlessness etc.

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11/16/01 ¹³ Claims 6, 12, 21 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al and Balandrin et al as applied to claim 1-5, 7-11, 14-20, 22-27 and 29-34 above, and further in view of Pankhania et al (5,415,871).

Neither Balandrin nor Rork teach xanthan gum as a gelling agent.

Pankhania teaches xanthan gum as a gelling agent in sustained formulations for various pharmaceutically active agents such as sedatives, cardiovascular agents etc (col. 4, lines 25-45). Pankhania suggests that xanthan gum hydrates and swells upon exposure to water, to form a gel, and allows a slow and sustained release of the active agent into the body, for as long as 24 hours or longer (col. 2 and col. 4). Pankhania also teaches that xanthan gum avoids the problems of hydrating too rapidly or too slowly and thus does not exhibit the problems of breaking up of the tablet (col. 2). Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use xanthan gum a gel forming polymer in the sustained release composition of Rork, containing diethylisovaleramide (Rork) or isovaleramide (Balandrin), because

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Pankhania suggests that xanthan gum as a gelling agent exhibits optimum hydration properties and the sustained release of the drug from xanthan gum containing formulation has a release profile which is independent of temperature, pH and also allows a steady diffusion of the drug.

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Lakshmi S. Channavajjala

November 14, 2001


Colhamudi S. Kishore, PhD
Primary Examiner
Group 1609

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